

## **REMARKS**

### **I. Introduction**

Claims 21, 22, 24-30 and 32-43 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

### **II. Rejection of Claims 21, 22, 24-28, 30, 33 and 35-43 Under 35 U.S.C. § 102(b)**

Claims 21, 22, 24-28, 30, 33 and 35-43 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 6,705,318 ("Brain"). Applicant respectfully submits that Brain does not anticipate the present claims for the following reasons.

Claim 21 relates to an oral airway. Claim 21 recites that the oral airway includes an elongate tubular member having a distal end and a proximal end. Claim 21 also recites that the oral airway includes an enlarged mask opening portion at the distal end of the elongate tubular member for insertion into the mouth and pharynx of a patient with the proximal end of the elongate tubular member adapted to extend from the mouth of the patient. Claim 21 recites that the mask opening portion has walls forming an enlarged proximal portion tapering to a smaller leading distal portion. Claim 21 also recites that the leading distal portion leads the mask opening portion as the mask opening portion is inserted into the mouth and pharynx of the patient. Claim 21 recites that there is an opening separating the walls at the leading distal portion of the mask opening portion. Claim 21 recites that the oral airway includes a grate partially obstructing the opening. Claim 21 has been amended herein without prejudice to recite the grate restrains any anatomical portions of the patient from entering the opening. Support for this amendment can be found, for instance, at page 14, lines 29-32 of the Specification which states that "[t]he bars 143 act to restrain any anatomical portion ... from entering into and blocking or partially blocking ... the mask opening 111."

Claim 30 relates to an oral airway. Claim 30 recites that the oral airway includes an elongate tubular member having a distal end and a proximal end. Claim 30 recites that the oral airway includes an enlarged mask opening portion at the distal end of the elongate tubular member for insertion into the mouth and pharynx of a patient with the proximal end of the elongate tubular member adapted to extend from the mouth of the patient. Claim 30 recites that the mask opening portion has walls forming an enlarged

proximal portion tapering to a smaller leading distal portion. Claim 30 recites that the leading distal portion leads the mask opening portion as the mask opening portion is inserted into the mouth and pharynx of a patient. Claim 30 recites that there is an opening separating the walls at the leading distal portion of the mask opening portion. Also, claim 30 has been amended herein without prejudice to recite that the oral airway includes a grate partially obstructing the opening to restrain any anatomical portions of the patient from entering the opening. Support for this amendment is set forth above. Claim 30 recites that the grate is inclined between the walls so that as a patient's epiglottis is engaged by the grate during insertion of the mask opening portion into the hypopharynx the epiglottis slides up the grate and into abutment with a wall of the mask opening portion, the grate being made of a flexible material that is rigid enough to slide the epiglottis into abutment with the wall of the mask opening portion as the mask opening portion is inserted into the hypopharynx. Claim 30 recites that the flexible grate material defines apertures between bars of the grate.

Claim 38 relates to a method of providing an oral airway to a patient. Claim 38 recites that the method includes the step of providing an elongate tubular member having a distal end and a proximal end with an enlarged mask opening portion at the distal end of the elongate tubular member for insertion into the mouth and pharynx of a patient with the proximal end of the elongate tubular member extending from the mouth of the patient, the mask opening portion having walls forming an enlarged proximal portion tapering to a smaller distal portion with a leading opening separating the walls at the distal end of the mask opening portion. Claim 38 has been amended herein without prejudice to recite that a grate partially obstructs the leading opening to restrain any anatomical portions of the patient from entering the leading opening. Support for this amendment is set forth above. Claim 38 recites that the method includes the step of inserting the mask opening portion into the mouth of the patient. Claim 38 recites that the method includes the step of axially advancing the mask opening portion to slide the epiglottis up the grate. Claim 38 recites that the method includes the step of seating the mask opening portion with the proximal portion of the mask opening portion abutting the laryngeal opening of the patient, a wall at the proximal end of the mask opening portion abutting the epiglottis and the grate adjacent to the glottis.

It is respectfully submitted that Brain does not anticipate claims 21, 30 and 38 for at least the reason that Brain does not disclose, or even suggest, all of the features recited in claims 21, 30 and 38. For example, Brain does not disclose, or even suggest, a grate partially obstructing an opening to restrain any anatomical portions of the patient from entering the opening, as recited in claims 21, 30 and 38. The Specification states at page 14,

lines 22-23 that “the mask opening 111 is formed by a plurality of apertures 142.” The Specification also states at page 14, lines 25-28, that “[t]hese apertures are used to pass air, oxygen, anesthesia or other gases from the airway tube 200 through the mask portion 100 and into the patient’s larynx L.” The Specification also states at page 14, lines 28-29, that “[t]he apertures 142 are separated from one another by a series of bars 143 forming a grate.” The Specification states at page 14, line 29 - page 15, line 2, that “[t]he bars 143 act to restrain any anatomical portion ... from entering into and blocking or partially blocking, the mask opening 111, thereby preventing obstruction of the delivery or removal of gases from the respiratory system of the patient P.”

Brain relates to a disposable laryngeal mask airway device. Brain describes that “two spaced elongate parallel bars 55, 56 [s]ymmetrically straddle the longitudinal sagittal plane of the mask (not shown) into which this component can be integrated.” Col. 31, lines 14-17. Brain further states that “[t]he purpose served by bars 55, 56 is to provide a measure of support for the drainage tube 43 as it passes over the lumen and as it alters course for distal-end symmetrical orientation with respect to the sagittal plane.” Col. 31, lines 17-21. Thus, the bars 55, 56 of Brain function to prevent the drainage tube 43 from entering the lumen of the mask when the drainage tube 43 is preassembled with the mask portion, not to restrain any anatomical portions of the patient from entering the opening. On the contrary, the bars 55, 56 of Brain are spaced apart from any anatomical portions of the patient by the expanded envelope portion 41, and thus during operation never even contact any such anatomical portions.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Brain does not anticipate claims 21, 30 and 38, because Brain does not disclose, or even suggest, all of the features recited in these claims.

As for claims 22, 24-28, 33, 35-37 and 39-43, each of which ultimately depends from and includes all of the limitations of a respective one of claims 21, 30 and 38, it is respectfully submitted that Brain does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claims 21, 30 and 38.

**III. Rejection of Claims 21, 22, 24-26, 28, 30, 33  
35-37 and 41-43 Under 35 U.S.C. § 102(b)**

Claims 21, 22, 24-26, 28, 30, 33, 35-37 and 41-43 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,265,621 (“McVey”). Applicant respectfully submits that McVey does not anticipate the present claims for the following reasons.

It is respectfully submitted that McVey does not anticipate claims 21 and 30 for at least the reason that McVey does not disclose, or even suggest, all of the features recited in claims 21 and 30. For example, McVey does not disclose, or even suggest, a mask opening portion that is inserted into the mouth and **pharynx** of a patient, as recited in claims 21 and 30. As set forth above, the Specification states at page 14, lines 22-23 that “the mask opening 111 is formed by a plurality of apertures 142.” The Specification also states at page 14, lines 25-28, that “[t]hese apertures are used to pass air, oxygen, anesthesia or other gases from the airway tube 200 through the mask portion 100 and into the patient’s larynx L.” The Specification further states at page 20, lines 4-7, that “[the airway tube] seats in the area above the entrance to the esophagus E against ... [a] portion of the pharynx.”

McVey relates to a tip for a dental aspirator. McVey describes that “screen 15 is located in a plane corresponding to the plane of the outer edge 11 across tube 10.” Col. 2, lines 62-64. McVey states that “[t]he face of screens 15 is formed as grid, having intersecting bars perpendicular to one another and forming interspersed apertures.” Col. 3, lines 4-6. McVey also states that “one end of the tube 10 is fitted within the outer end of a suction hose ... and the remaining or outer end of the tube is normally unobstructed and open for use **within the mouth.**” Col. 2, lines 20-23, emphasis added. McVey further states that “[the vents 13] provide vacuum relief to the interior of the tip and aspirator tube, thereby preventing attachment of the tip to **mouth tissue** while in use.” Col. 3, lines 22-25, emphasis added. Thus, while the tip having the screens 15 of McVey are inserted into a patient’s mouth, **they are not capable of being, nor intended to be, inserted into a patient’s pharynx.** On the contrary, McVey explicitly states at col. 4, lines 6-10, that “[it] relates to a tip for an aspirator [that] serves the basic function of permitting the aspirator to withdraw liquid **from the patient’s mouth**, while preventing solid items from being drawn to the mechanical vacuum pump unit”, and thus McVey never even contemplates that the end of the tube 10 may be inserted beyond the mouth of the patient, e.g., into the pharynx, during

operation since doing so would fail to perform the stated function of removing liquid from the patient's mouth.

Since McVey does not disclose, or even suggest, all of the features recited in claims 21 and 30, it is respectfully submitted that McVey does not anticipate claims 21 and 30. As for claims 22, 24-26, 28, 33, 35-37 and 41-43, each of which ultimately depends from and includes all of the limitations of a respective one of claims 21 and 30, it is respectfully submitted that McVey does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claims 21 and 30.

**IV.            Rejection of Claims 21, 22, 24-26, 28, and 41-43 Under 35 U.S.C. § 102(b)**

Claims 21, 22, 24-26, 28 and 41-43 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 2,677,375 ("Raiche"). Applicant respectfully submits that Raiche does not anticipate the present claims for the following reasons.

It is respectfully submitted that Raiche does not anticipate claim 21 for at least the reason that Raiche does not disclose, or even suggest, all of the features recited in claim 21. For example, Raiche does not disclose, or even suggest, an oral airway including a mask opening portion that is inserted into the mouth and pharynx of a patient, as recited in claim 21. As set forth above, the Specification states at page 14, lines 22-23 that "the mask opening 111 is formed by a plurality of apertures 142." The Specification also states at page 14, lines 25-28, that "[t]hese apertures are used to pass air, oxygen, anesthesia or other gases from the airway tube 200 through the mask portion 100 and into the patient's larynx L." The Specification further states at page 20, lines 4-7, that "[the airway tube] seats in the area above the entrance to the esophagus E against ... [a] portion of the pharynx."

Raiche relates to a balloon catheter. Raiche describe that "[t]he distal end 17 of the catheter is open ... and has a foraminated closure formed of crossed rubber strips 19, 20 ... which provide foraminated drainage inlets 21 to the drainage channel." Col. 1, line 55 – col. 2, line 5. Raiche describes that "[i]t has been found desirable to provide a catheter construction of the balloon type which has no distal tip, as some patients have inflamed or sensitive bladders." Col. 1, lines 32-35, emphasis added. Thus, the distal end 17 of Raiche having the strips 19, 20 are inserted into a patient's bladder, not into the mouth and pharynx of a patient. Furthermore, because the distal end 17 of Raiche having the strips 19, 20 is inserted into a patient's bladder, the device of Raiche does not constitute an oral airway.

There is no disclosure or suggestion whatsoever that the catheter of Raiche is capable of being, or intended to be, inserted into a patient's mouth or pharynx.

Since Raiche does not disclose, or even suggest, all of the features recited in these claim 21, it is respectfully submitted that Raiche does not anticipate claim 21. As for claims 22, 24-26, 28 and 41-43, each of which ultimately depends from and includes all of the limitations of independent claim 21, it is respectfully submitted that Raiche does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 21.

**V. Allowable Subject Matter**

Applicant gratefully acknowledges that claims 29, 32 and 34 would be allowable if rewritten in independent form. However, for the reasons set forth above, Applicant respectfully maintains that independent claims 21 and 30 are themselves allowable, and thus, that claims 29, 32 and 34 are allowable in their current form.

**VI. Request For Interference**

Applicants respectfully request that, since it is believed that all of the pending claims of the present application are now in condition for allowance, an interference be declared between claims 21, 22, 24-30 and 32-43 of the present application and claims 1 to 39 of U.S. Patent No. 6,386,199 ("the '199 patent"), for the reasons set forth in Applicant's previously filed "Amendment and Request for Interference" filed in the U.S. Patent and Trademark Office on May 13, 2003 and in each subsequent Request for Interference filed thereafter, and additionally for the reasons set forth below.

As set forth above, Applicant has amended claims 21, 30 and 38 to recite that the grate that partially obstructs the leading opening "restrains any anatomical portions of the patient from entering the leading opening." The Specification states at page 14, lines 22-23, that "the mask opening 111 is formed by a plurality of apertures 142." In addition, the Specification states at page 14, lines 28-29, that "[t]he apertures 142 are separated from one another by a series of bars forming a grate." The Specification states at page 17, lines 27-33 that "[t]he bars and grates 143 act to restrain any anatomical portion ... from entering into and blocking or partially blocking, the mask opening 111', thereby preventing obstruction of the delivery or removal of gases from the respiratory system of the patient P." Still further, the Specification states at page 18, lines 22-25, that "the apertures 142 between the bars 143 increase the likelihood of establishing a ventilation path even when substantial mucousa is present." The Specification further states that "the bars 143 may preferably form an angled surface 143a which will assist in the insertion of any tube into the larynx via the airway tube 200."

Claim 18 of the '199 patent recites that “the grate being made of a flexible material that is rigid enough to slide the epiglottis into abutment with the anterior wall of the wedge-shaped housing as the wedge-shaped housing is inserted into the hypopharynx.” Claim 37 of the '199 patent recites that “the grate is made of a flexible material that is rigid enough to slide the epiglottis into abutment with an anterior wall of the elongate tubular member as the wedge-shaped housing is inserted into the hypopharynx.” The '199 patent states that “FIG. 7A further includes a plurality of bars 452 forming a grate over the leading opening 454 [wherein] the bars are rigid enough to support the epiglottis.” Column 10, lines 43-50. In addition, the '199 patent states that “a grate may cover the opening to keep the epiglottis and other tissue out of the opening.” Column 5, lines 29-30, emphasis added. Therefore, the respective bars of the gratings, and the apertures/gaps situated between the bars of the grating, of the present application and the '199 patent are described as performing the same function, e.g., preventing any anatomical portion from entering into and blocking or partially blocking the mask opening.

Applicant therefore respectfully maintains that, by virtue of the fact that the bars of the gratings, and the apertures/gaps situated between the bars of the grating, of the present application and the '199 patent perform the same function and in the context of the claims are directed to the same patentable invention, an interference should be declared between claims 21, 30 and 38 of the present application — which include the limitation of “the grate partially obstructing the leading opening to restrain any anatomical portions of the patient from entering the leading opening” — and claims 18 and 37 of the '199 patent — which include the limitations of “the grate being made of a flexible material that is rigid enough to slide the epiglottis into abutment with the anterior wall of the wedge-shaped housing as the wedge-shaped housing is inserted into the hypopharynx” and “the grate is made of a flexible material that is rigid enough to slide the epiglottis into abutment with an anterior wall of the elongate tubular member as the wedge-shaped housing is inserted into the hypopharynx”, respectively.

## **VII. Conclusion**

Applicants respectfully submit that all of the pending claims of the present application are now in condition for allowance. Prompt reconsideration and allowance of the present application, and the declaration of the above-referenced interference proceeding, are therefore earnestly solicited.

**VIII. Fees**

The Commissioner is authorized to charge any necessary fees or credit any overpayments under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

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